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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,509	05/21/2002	Eric Paul Krenning	0702-020040	6829

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EXAMINER	
HUI, SAN MING R	
ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/031,509	KRENNING ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53,55-58,60-63,65 and 66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53,55-58,60-63,65 and 66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 19, 2007 has been entered.

Claims 65-66 have been added.

Claims 53, 55-58, 60-63 and 65-66 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 53, 55-58, and 60-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,648,059 ('059), US 5,843,894 ('894) and Hammond et al. (Br. J. Cancer, 1993;67:1437-1439) from IDS filed April 21, 2003).

'059 teaches L-lysine, arginine and ornithine as useful as inhibiting the retention and reabsorption of therapeutic immunoconjugate such as antibodies and monoclonal antibodies (See claims 1, 2, 3, and 5). '059 teaches protein uptake by the kidney as

decreased when a dosage of 10mg lysine is administered to a rat animal (See col. 10-11, Examples I-III).

'894 teaches D-Lysine as useful in a method of reducing the uptake of antibody fragments (See the abstract). '894 teaches the effective dosage of lysine and polysine solution effective in reducing uptake of antibody fragments as 2-35g/L and 10-25g/L respectively (See col. 6, lines 15-28).

Hammond teaches amino acids 4.93g/L of lysine and 17.6 g /L of arginine as useful in blocking renal tubular uptake of somatostatin (See page 1437, col.2, Materials and Methods section).

The references do not expressly teach the herein claimed dosage of lysine and arginine.

It would have been obvious to one of ordinary skill in the art at the time the invention made to adjust amount of the herein claimed active to the herein claimed dosage.

One of ordinary skill in the art would have been motivated to adjust amount of lysine, polylysine, and arginine to the herein claimed dosage since the optimization of the result parameters as within the purview of the skilled artisan, absent evidence to the contrary.

Response to Arguments

Applicant's arguments filed September 21, 2006 averring the cited prior arts' failure to teach both lysine and arginine together in a method of reducing protein

reuptake by the kidney have been considered, but are not found persuasive. Examiner notes that '059 teaches the co-administration of lysine or polylysine with arginine (See claim 5), which are essential for inhibiting the immunoconjugate renal reuptake. It is not clear why applicant would state that '059 being teaching away since the cited prior arts, as a whole, suggest the very same agents in reducing the renal reuptake of proteins. The basis of the combining both herein recited agents in the method and composition to reducing protein reuptake by the kidney is based on the fact that the herein claimed amino acids are known to be useful to inhibit renal protein reuptake individually. It flows logically to combine these two amino acids together in a method or composition useful for the very same purpose, especially the specific combination of amino acids is known (See claim 5 of '059).

Applicant's arguments filed September 21, 2006 averring the cited prior arts' failure to teach the herein claimed dosages have been fully considered but they are not persuasive. Examiner notes that the dosages of the amino acids employed in the instant invention are well within or overlapped with the range disclosed by the cited prior arts. Absent evidence of the criticality of the dosages herein claimed, optimization of the result parameters (such as dosages and dosing regimen) as within the purview of the skilled artisan.

Claims 65-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over '059, '894, and Hammond as applied to claims 53, 55-58, and 60-63 above, and further in view of Remington Pharmaceutical Sciences, 1990, 18th ed., pages 1481-1498.

'059, '894, and Hammond suggest the method and composition of reducing the renal reuptake of proteins.

'059, '894, and Hammond do not expressly teach the herein claimed osmolarity.

Remington teaches the osmolarity is depending on the agents and their concentration in the dosage (See for example pages 1482-1483). Remington also teaches the osmolarity of various commonly used parenteral formulations, in which the osmolarity ranges form around 300 to 800mOsmol/ml (See page 1483, col. 2).

It would have been obvious to one of ordinary skill in the art at the time of invention to adjust the osmolarity of the instant pharmaceutical composition.

One of ordinary skill in the art would have been motivated to adjust the osmolarity of the instant pharmaceutical composition since adjusting the osmolarity of the pharmaceutical composition as routine. Furthermore, the less solute is in the composition, the osmolarity decreases. Therefore, Hammond teaches the cocktail of amino acids having the osmolarity of 880, if only two of the amino acids are employed, then osmolarity is reasonably expected to be decreased, absent evidence to the contrary. Therefore, the optimization of the osmolarity would be considered obvious as being within the purview of the skilled artisan.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

San-ming Hui
Primary Examiner
Art Unit 1617